K080824

MAY - 7 2008

510(k) SUMMARY of Safety and Effectiveness

I. Applicant Information:

Date Prepared:	March 21, 2008
Submitter:	Medtronic, Inc.
Address:	7611 Northland Drive Brooklyn Park, MN 55428
Establishment Registration No.	2184009
Contact Person:	Preeti Jain Director of Regulatory and Clinical Affairs
Telephone Number:	(763) 391-9533
Fax Number:	(763) 391-9100

II. Device Information:

Trade Name:	Bio-Console® 560
Common Name:	Cardiopulmonary bypass pump speed control
Classification Name:	Control, Pump Speed, Cardiopulmonary Bypass
Classification:	Class II, 21 CFR 870.4380
Product Code:	DWA
Predicate Device:	Medtronic Bio-Console® 560 510(k) No. K070286, Reg. No. 870.4380; Product Code: DWA

Device Intended Use: The Medtronic centrifugal blood pumping system is intended to pump blood through the extracorporeal bypass circuit for extracorporeal support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours).

Device Description:	The Bio-Console® 560 is an extracorporeal blood pumping console consisting of a Base Unit with a display and a User Interface (touch screen) with integrated flow control knob. In order to perform its intended function, the Bio-Console 560 is compatible with the Medtronic External Drive Motor, disposable Centrifugal Pump, Flow Transducer with disposable Insert, and Emergency Handcrank.
Intended Use:	The Medtronic centrifugal blood pumping system is intended to pump blood through the extracorporeal bypass circuit for extracorporeal support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours).
Comparison to Predicate Device:	The Bio-Console 560 has the same intended use, hardware design and basic software as the previously cleared Bio-Console 560. The only change to the device is the incorporation of some minor software modifications, which modify the way the Base Unit and User Interface control sensors and alarms, control the Coast Speed and ensure that the Pump Speed is greater than the Coast Speed to open the clamp.
Test Data:	Software verification and validation testing confirms that the function of the Bio-Console 560 and its software-controlled functional characteristics are substantially equivalent to the predicate device. All test data obtained satisfied the documented product and performance specifications.
Summary:	Based upon the technical information, intended use, and *in vitro* verification and validation information provided in previous pre-market notifications, the Bio-Console 560 addressed in this submission has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2008

Medtronic, Inc.
c/o Ms. Preeti Jain
Director of Regulatory and Clinical Affairs
7601 Northland Drive
Minneapolis, MN 55428

Re: K080824
Bio-Console® 560
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary bypass pump speed control
Regulatory Class: Class II (two)
Product Code: DWA
Dated: March 21, 2008
Received: March 24, 2008

Dear Ms. Jain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K080824

Device Name: **Bio-Console® 560**

Indications for Use:

The Medtronic centrifugal blood pumping system is intended to pump blood through the extracorporeal bypass circuit for extracorporeal support for periods appropriate to cardiopulmonary bypass procedures (up to 6 hours).

Prescription Use _X_ AND/OR Over-the-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080824